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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,616	08/09/2006	George F. Vande Woude	28927.0018	1900

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,616	VANDE WOUDE ET AL.	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-13,16-18,20-22,26,28-34,37,38 and 40-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 5, 7-13, 16-18, 20-22, 26, 28-34, 37, 38, 40-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 1/6/2006 has been entered. Claims 1, 5, 7-13, 16-18, 20-22, 26, 28-34, 37, 38, 40-46 are currently pending and are addressed herein.

The response filed 5/22/2009 is acknowledged. Applicants are correct that a preliminary amendment was filed 1/6/2006, but that the previous Action did not acknowledge the preliminary amendment. Therefore, the Election/Restriction requirement was based on an improper claim set. Therefore, the previous Election/Restriction requirement is hereby withdrawn, and a new election/Restriction requirement is set forth for the reasons set forth below.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 11, 12, 20, 21, drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of TSP-1 or a derivative thereof.

Group II, claim(s) 1, 11, 12, 20, 21, drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of TSP-1 agonist or mimic.

Group III, claim(s) 1, 9-12, 20, 21, drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of an inhibitor of HGF/SF.

Group IV, claim(s) 1, 9-12, 20, 21, drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of an inhibitor of Met (the HGF/SF receptor).

Group V, claim(s) 1, 5, 7, 8, 11, 12, 20, 21,drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of an inhibitor of VEGF.

Group VI, claim(s) 1, 5, 7, 8, 11, 12, 20, 21,drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of an inhibitor of the VEGF receptor.

Group VII, claim(s) 13, 16-18, drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of an inhibitor of the MAPK pathway and an agent that inhibits upregulation of VEGF.

Group VIII, claim(s) 13, 16-18, drawn to a method of inhibiting tumor angiogenesis comprising administering an effective amount of an inhibitor of the MAPK pathway and an agent that inhibits down-regulation of TSP-1.

Group IX, claim(s) 22, 32, drawn to a composition comprising TSP-1 or a derivative thereof.

Group X, claim(s) 22, 32, drawn to a composition comprising a TSP-1 agonist/mimic.

Group XI, claim(s) 22, 30, 31, 32, 43-46, drawn to a composition comprising an inhibitor of HGF/SF.

Group XII, claim(s) 22, 30, 31, 32, 43-46, drawn to a composition comprising an inhibitor of Met (HGF/SF receptor).

Group XII, claim(s) 22, 26, 28, 29, 32, 33, 43-46, drawn to a composition comprising an inhibitor of VEGF.

Group XIII, claim(s) 22, 26, 28, 29, 32, 33, 43-46, drawn to a composition comprising an inhibitor of VEGF receptor.

Group XIV, claim(s) 34, 37-42, drawn to a composition comprising at least two inhibitors of the MAPK pathway and an agent that inhibits upregulation of VEGF.

Group XV, claim(s) 34, 37-42, drawn to a composition comprising at least two inhibitors of the MAPK pathway and an agent that inhibits upregulation of VEGF receptor.

Group XVI, claim(s) 34, 37-42, drawn to a composition comprising at least two inhibitors of the MAPK pathway and an agent that inhibits down-regulation of TSP-1.

1. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

First, 37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I, is considered the main invention.

The instant claims are drawn to two different categories of invention: The methods of Groups I-XIII and the composition of Groups IX-XVI. 37 CFR 1.475(b), as it applies to the instant case, is interpreted as indicating that unity of invention may exist between different categories of inventions ONLY if the claims are drawn to a product and a process of using said product (i.e., if the main invention, Group I, is a product, and the second category of invention, Group II, is a process of using said product). Since the main invention in the instant case is a process of using a product, then the instant categories of inventions do not meet the criteria of 37 CFR 1.475(b), and thus, unity of invention does not exist, by definition.

Second, if the common technical feature linking the claims do not make a contribution over the prior art, then the technical is not a "special technical feature" and unity of invention does not exist. In the instant case, claim 1 is considered to be the main invention. However, claim 1 does not make a contribution over the prior art, as evidenced by WO 01/66114, which was cited as an "X" reference in the International Search Report of the National Stage of the instant case. Since claim 1, the main invention, is not novel, there is no special technical feature linking the Inventions.

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claim encompass the following species:

1) VEGF inhibitor or VEGF receptor inhibitor and a single species thereof as listed in claims 5, 7, 8, 28, 29;

2) HGF/SF inhibitor or Met inhibitor and a single species thereof as listed in claims 9, 10, 30, 31, 32;

3) A single MEK inhibitor as listed in claims 16, 17, 18, 37, 38;

To be clear, Applicants are required to elect: (1) VEGF inhibitor and then a single specific VEGF inhibitor or VEGF receptor inhibitor and a single specific VEGF receptor inhibitor; (2) HGF/SF inhibitor and a single specific HGF/SF inhibitor or Met inhibitor and a single specific Met inhibitor; and, (3) a single specific MEK inhibitor.

As such, Applicant is required, in reply to this action, to elect a single species from each of the groups of species listed above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 5, 7-13, 16-18, 20-22, 26, 28-34, 37, 38, 40-46.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The claimed molecules are structurally different from one another. That is, each species has a distinct chemical structure that is distinct from the chemical structures of the other species. In order for the species to have unity of invention, the species must be structurally and functionally related. In the instant case, the species are structurally distinct, and as such no two species would have the exact same function; therefore, unity of invention does not exist for the claimed species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635